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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,622	05/11/2001	Hiromu Sugino	2001-0559A	6107

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EXAMINER

ANDRES, JANET L

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 06/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/831,622

Applicant(s)

SUGINO, HIROMU

Examiner

Janet L. Andres

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 7-14, 17-23 and 25-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 15, 16 and 24 is/are rejected.
- 7) ☒ Claim(s) 24 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>1</u> | 6) <input type="checkbox"/> Other: |

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DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in Paper No. 15 is acknowledged. The traversal is on the ground(s) that unity of invention is present between protein and DNA, methods of making the protein, and methods of using the protein. This is not found persuasive because, as is set forth on p. 2 of the office action of paper no. 14, polypeptides substantially identical to the instantly claimed polypeptide are known in the art. Therefore this polypeptide is not a special technical feature, as it does not define a contribution over the prior art. Thus unity of invention is not present because there is no special technical feature linking the two inventions. Similarly, there is no unity of invention between claims drawn to methods of making the polypeptide and the polypeptide, because the polypeptide is not a contribution over the prior art and is thus not the special technical feature linking the claims in Group I. See PCT rule 13:

13.1 Requirement

The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention").

13.2 Circumstances in Which the Requirement of Unity of Invention Is to Be Considered Fulfilled

Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

Claim 19 was not included in Group I because it is considered to have a different special technical feature from the claims that are included in Group I for the reasons set forth on p. 3 of

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the office action of paper no. 14. Since the polypeptide itself does not represent a contribution over the prior art it cannot serve as the special technical feature linking the method claims.

The requirement is still deemed proper and is therefore made FINAL. Claims 1-30 are pending in this application. Claims 7-14, 17-23, and 25-30 are withdrawn from consideration as being drawn to a non-elected invention.

Applicant has pointed to claim 2 and SEQ ID NO: 6 as exemplifying representative species. However, there was no requirement for an election of species because it was noted that SEQ ID NO: 6 is a fragment of SEQ ID NO: 5, lacking the first 50 amino acids, and thus two could be searched together.

Information Disclosure Statement

2. The information disclosure statement filed 11 May 2001 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each document listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

Specification

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The title identifies the invention only as "novel protein". Novelty is a legal concept and does not describe the invention claimed. Novelty is required of all claimed inventions before they are issued as patents. To use the term in the title would imply merit in this regard without actual examination. Accordingly, though

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MPEP 606.01 does not specifically refer to "novel", it is similar to the term "improve" which also implies merit without examination.

Claim 24 is objected to because of the following informalities: This claim depends from claims drawn to non-elected inventions. Appropriate correction is required. Claim 24 is also objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim may not depend from another multiple dependent claim. See MPEP § 608.01(n). Claim 24 is examined as if it depended only from claim 16.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1-6 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Since these claims do not require that the protein be isolated, they encompass products of nature.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-6, 15, 16, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Hirao et al., J. Biol. Chem. 1998, vol. 273, no. 33, pp. 21105-21110.

Hirao et al. teaches a protein that is 98.5% identical to instant SEQ ID NO: 6. While Applicant has not defined what percent identity is considered to be substantial, the protein of

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Hirao et al. clearly exhibits a high degree of similarity to both SEQ ID NO: 6 and the longer sequence, SEQ ID NO: 5, thus anticipating the limitations of claims 1 and 2. PDZ domains and WW domains are explicitly taught on p. 21106, column 2, and are further an inherent feature of the protein, as are its binding characteristics. A protein so nearly identical to that disclosed by Applicant would have the same binding characteristics, regardless of whether they are disclosed or not, inherently anticipating the binding characteristics of claims 3-5. The protein of Hirao et al. is also expressed solely in the brain, as it taught on p. 21106, column 2. Peptide portions, in the form of the various domains, are also taught in column 2 of p. 21106. The use of the two hybrid system and of co-precipitation to identify proteins that bind to this protein are taught on p. 21107, column 2, through p. 21109, column 1, anticipating the limitations of claims 15, 16, and 24.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-6, 15, 16, and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims encompass polypeptides that are “substantially identical” to the disclosed sequences. There is no definition in the specification of what percent identity is considered to be substantial, and thus the skilled artisan would be unable to determine what polypeptides were encompassed.

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NO CLAIM IS ALLOWED.

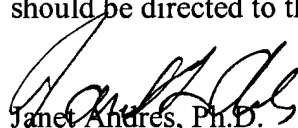
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to yvonne.eyler@uspto.gov.

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Janet Andres, Ph.D.
Patent Examiner

June 10, 2003